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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/529,369	06/08/2001	Ilse Bartke	3200.009US0	3099

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EXAMINER
WEBER, JON P

ART UNIT	PAPER NUMBER
1651	14

DATE MAILED: 04/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/529,369	BARTKE ET AL.	
	Examiner	Art Unit	
	Jon P Weber, Ph.D.	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 January 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) *1-6 and 12-15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-11 and 16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Status of the Claims

Claims 1-16 have been presented for examination.

Election/Restrictions

Applicant's election with traverse of Group II, claims 7-11 and 16 in Paper No. 13, filed 17 January 2003 is acknowledged. The traversal is on the ground(s) that this application is filed under 371 and examiner has not met the burden for lack of unity because the special technical feature is not NGF, but treatment of diseases in which demyelination occurs. This is not found persuasive because a special technical feature must be shared by all the alleged inventions groups; the treatment of diseases is not shared with the composition claims (the functional intended use does not materially change the composition or detract from its other uses). The only technical feature shared by all groups is NGF. Since it has been established that NGF is not a contribution over the art, lack of unity is proper.

The requirement is still deemed proper and is therefore made FINAL. Claims 1-6 and 12-15 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Group, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 13.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 7-11 and 16 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 7-11 and 16 of copending Application No. 09/854,142. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented. Cancellation of the conflicting claims in the copending application would obviate this rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7, 10 and 16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for specific fragments of NGF (2.5S and 7S), does not reasonably provide enablement for any "active" fragment or "analogue". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and or use the invention commensurate in scope with these claims.

The instant claims are broadly drawn to any "active fragment" or "analogue" of NGF. However, aside from the specific fragments, C, no fragments have been identified that function in the claimed method. In fact the particular residues necessary for the structure and function of the "active fragments" have not been identified or disclosed. In other words, the residues of NGF

that may be deleted, added or substituted and still retain the desired activity have not been identified or disclosed. No general teaching of suitable analogues has been presented.

The disclosure alleges that active fragments can be used to prevent demyelination. However, no examples of active fragments were even tested for their ability to reduce demyelination let alone prevent demyelination. A person of ordinary skill in the art would have to test each every putative active fragment for the desired ability to reduce and prevent demyelination. Given the complexity and difficulty of performing the assay for activity, it would require undue experimentation to make and test all possible active fragments for the claimed activity. Those aspects of NGF that give rise to the allegedly newly discovered activity may not require the entire NGF molecule although the entire molecule is required to obtain the correct folding pattern of NGF for this activity. None of specifically recited fragments was tested for the claimed activity. The artisan would not know which fragments are likely on any structural or other basis. It would require an undue burden of experimentation to determine the residues that can be deleted, added or substituted to produce and active fragment and still retain the desired activity except for the deleted, except for 2.5S and 7S, or any general structural elements of an analogue. Accordingly, the claims are not commensurate in scope with the enabling disclosure with respect to active fragments or analogues.

Claims 9-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 recites "recombinant" which is vague and indefinite because it is not clear if the molecule is simply recombinantly produced or has been modified by recombinant techniques.

Claim 10 recites "further comprising" which lacks antecedent basis.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 7-11 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Althaus (WO 9303140).

Althaus (WO 9303140) discloses that a pharmaceutical composition comprising NGF or an active fragment thereof can be used as a treatment for diseases in which demyelination of nerve fibers occurs (page 4, second paragraph). Some of these diseases included are set forth in the paragraph connecting pages 4-5. Specific active fragments include NGF-ß, NGF-2.5S, and NGF 7S (page 2, third full paragraph). The NGF-ß may be human recombinant. The compositions may further comprise a protease inhibitor, preferably aprotinin which is also known under the brand name of Trasylol® (page 3, last paragraph).

Claims 7 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Unger et al. (EP 731,108).

Unger et al. (EP 731,108) discloses interval treatment of oligodendrocytes in multiple sclerosis with pharmaceutical compositions of human NGF-ß for the improved remyelination in nerve fibers compared to continuous treatment (recombinant NGF-ß is known).

These references are only representative a references that disclose NGF compositions.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon P Weber, Ph.D. whose telephone number is 703-308-4015. The examiner can normally be reached on daily, off 1st Fri, 9/5/4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 703-308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Jon P Weber, Ph.D.
Primary Examiner
Art Unit 1651

JPW
April 11, 2003